DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 21, 2015

Genadyne Biotechnologies, Inc.
Chien-Ming Goh
Vice President, Regulatory Affairs
16 Midland Avenue
Hicksville, NY 11801

Re: K143574
Trade/Device Name: Melodi Prime Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: March 27, 2015
Received: March 30, 2015

Dear Chien-Ming Goh,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143574

Device Name
Melodi Prime Breast Pump

Indications for Use *(Describe)*
The powered Melodi Prime Breast Pump is intended to express and collect milk from the breast of a lactating woman. This device is a double pump with a single pumping option; it is intended for a single user.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510k Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: April 21, 2015

Applicant and official correspondent:
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Name of Device

Melodi Prime Breast Pump
Classification Name: Powered breast pump (21 CFR 884.5160)
Regulation Class: Class II
Product Code: HGX

Predicate Device

Lucina-Melodi Powered Breast Pump (K102516)

Device Description

The Melodi Prime breast pump is a battery operated breast pump. It operates with 4 AA size batteries. It comes with a power adapter as it can be used with a power adapter without batteries as well. The power adapter does not charge the batteries.

The Melodi Prime breast pump is designed to be a single patient use device. It consists of a LCD display that allows the user to see the current settings of the device. It is an easy to use device, consist of 5 buttons (On/Off, + , - , Phase 1/ Phase 2, & Single/ Double Pumping).

The breast pump allows for single pumping and double pumping options. The suction hose connections are independent of each other. Inside the device, it consists of a PCB, motor and valve.

The accessories that comes with the device are from Ardo Medical AG. The PumpSets are approved under K141742.

Intended Use / Indications for Use

The powered Melodi Prime Breast Pump is intended to express and collect milk from the breast of a lactating woman. This device is a double pump with a single pumping option; it is intended for a single user.

Performance Data

The pressure level and cycles per minute remains consistent throughout the bench test and shows a constant and uniform behavior. Back flow tests confirm that the Melodi Prime Breast Pump can prevent back flow of the liquid from the Pump Set into the tubing.

The test subject, Melodi Prime Brest Pump and the breast shield set, is able to successfully prevent back flow of the liquid form the Pump Sets into the tubing and into the pump. The Pump Sets are also able to prevent liquid going out from the bottle to the pump.

The system was tested for more than 72 hours without any problems or errors.

Clinical Testing

No clinical data was required.

Predicate Device Comparison

Parameter	Subject device (K142479)	Predicate device (K102516)
Device name	Melodi Prime Breast Pump	Lucina-Melodi Powered Breast Pump
Intended use	Same as the predicate	Intended to express and collect milk from the breasts of lactating women.
Pumping configuration	Same as the predicate	Single or double
Anti-backflow mechanism	Same as the predicate	Diaphragm cover
Suction pressure	60-250 mmHg	50-250 mmHg
Suction control	Same as the predicate	Microprocessor
LCD	Same as the predicate	Yes
Power source	6V DC adapter Or four AA batteries	Adapter output 19V, 30W Or rechargeable lithium battery

Substantial Equivalence Discussion

- Intended use – The subject and predicate devices have the same intended use.
- Technological characteristics – Similarities between the subject and predicate devices
    - They both have single and double pumping options.

- They both are controlled by the microprocessor.
- They have comparable suction pressures.
- They have the same anti-backflow mechanism.
- They both have LCD.

- Technological characteristics – Differences between the subject and predicate devices

  - The subject device is different from the predicate device in power sources. However, the differences do not raise any concerns, because the subject device has passed electrical safety and electromagnetic compatibility (EMC) testing.

  - The subject and predicate devices may use different materials in user and milk contacting components. However, the PumpSets used in the subject device is a cleared device. Therefore, there are no any concerns on biocompatibility and food safety.

Therefore, the subject device is substantially equivalent to the subject device regarding safety and effectiveness.

Conclusions

Based on the information presented in this submission, it can be concluded that the Melodi Prime Breast Pump is equivalent to its predicate device, the Lucina-Melodi Powered Breast Pump (K102516) with respect to the intended use, materials, design and technological characteristics.